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NOTES

YRBS = Youth Risk Behavior Survey – high school students (items listed are on the national YRBS)

NYTS = National Youth Tobacco Survey – middle and high school students

MTF = Monitoring the Future Surveys – 8th, 10th, and 12th grade students (only 2 tobacco questions are on the core questionnaire: one deals with lifetime use and the other deals with current patterns of use. All others are on subsets of the full sample, meaning that they provide less precise estimates)

NHSDA = National Household Survey on Drug Abuse – ages 12 years and older (2000 questionnaire)

NHIS = National Health Interview Survey – ages 18 years and older (NHIS 2000 Cancer Supplements)

BRFSS = Behavioral Risk Factor Surveillance Survey – ages 18 years and older; state-specific estimates

CPS = Current Population Survey – ages 15 years and older; state-specific estimates (note that CPS uses proxy estimates for some selected sample persons; proxy reports of smoking for teenagers are more likely to lead to under estimates of prevalence than self-reports)

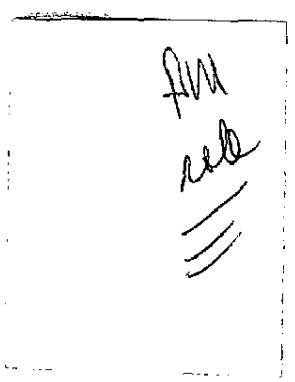
VARIABLE	YRBS	NYTS	MTF	NHSDA	NHIS	BRFSS	CPS
Self-esteem			X				
Stress			X				
Depressive symptoms/other mental health indicators				X			
Perception of youth smoking prevalence			X				
Family/peer use of tobacco		X		X			
Parental relationship quality			X				
Parental monitoring			X				
Anti-tobacco socialization by parents		X					
Home bans							X
Home exposure to ETS					X		
School/worksite indoor air policy					X		
Outcome of last purchase attempt		X		X			
Source(s) of cigarettes		X	X				
Price paid for tobacco		X		X			
Usual brand/brand history		X	X	X			
Promotional items (own/would use or wear)		X					
Perceived risks of smoking		X	X	X	X		
Harm reduction mindset		X			X		
Risk orientation			X	X			
Functional utility		X					
Approval/disapproval				X			
Social environment			X	X			
School performance		X	X				
Religiosity		X	X				
Receptivity to marketing		X					

Table 6-1 Inclusion of Key Variables Regarding Tobacco Use on Existing National Surveys

VARIABLE	YRBS	NYTS	MTF	NHSDA	NHIS	BRFSS	CPS
Susceptibility/intentions		X	X	X			
Ever smoke cigarettes (even a puff)	X	X	X	X			
Age/grade of first try/first whole cigarette	X	X	X	X			
Ever smoke regularly/daily	X	X	X	X			X
Age/grade first smoked regularly/daily			X	X	X		X
Smoked 100+ cigarettes		X		X	X	X	X
Detailed # lifetime cigarettes		X					
Current Use	X	X	X	X	X	X	X
Patterns of current use	X	X	X	X	X	X	X
Level of dependence		X		X			
Duration of abstinence		X		X	X	X	X
Ever tried to quit	X				X		X
# prior attempts (ever)		X			X		
Quit attempt in previous year		X			X		X
# attempts (previous year)							X
Duration of previous quit attempt (most recent)		X					
Stage of change					X		X
Motivation to quit		X					
MD discuss tobacco		X			X		
MD advise quitting							X
Dentist discuss tobacco		X					
Dentist advise quitting							X
Method(s) used to quit		X			X		
Ever use other tobacco products		X		X	X	X	
Current use of other tobacco products	X	X	X	X	X	X	X

PREPs to the public's health status, and to inform policy initiatives and regulatory judgments. Thus, the system will need to estimate relative changes in the prevalence of tobacco use, as well as changes in the relative harm to users of PREPs. Strong data accumulated over many years are necessary to judge if PREPs (or classes of PREPs) contribute to maximizing the health of the public. Public health officials will need to determine if the prevalence of tobacco use drops to a level at or near what it would have in the absence of PREPs and if the health benefits (if any) caused by switching to PREPs compensate for any decrement in prevalence reduction that they cause. This will be a challenging process, but one that will only be possible if optimal data collection systems are swiftly put in place. Until surveillance mechanisms that would enable prospective assessment of the public health impact are in place, it might be prudent to take an especially risk averse position regarding communications and claims (see Chapter 7). Given this approach, **the committee makes the following recommendations:**

1. There is an urgent need for a national comprehensive surveillance system that collects information on a broad range of elements necessary to understand the population impact of tobacco products and PREPs, including attitudes, beliefs, product characteristics, product distribution and usage patterns, marketing messages such as harm reduction claims and advertising, the incidence of initiation and quitting and non-tobacco risk factors for tobacco-related conditions. There should be surveillance of major smoking-related diseases as well as construction of aggregate population health measures of the net impact of conventional product and PREPs.
2. The surveillance system should consist of mandatory, industry-furnished data on tobacco product constituents, additives, and population distribution and sales.
3. Resources should be made available for a program of epidemiological studies that specifically address the health outcomes of PREPs and conventional tobacco products, built on a robust surveillance system and using all available basic and clinical scientific findings.



cancer causation and changing frequency may require ascertainment of other risk factors such as radon or occupational exposures. Monitoring coronary disease outcomes requires determination of major risk factors other than tobacco exposure, such as those noted in Chapter 13. It may not be the burden of the surveillance system to furnish all relevant risk factors for smoking-related conditions, but where possible, this would be helpful.

There are several limitations and issues with respect to applying surveillance systems to the assessment of tobacco product usage and health. As noted above, there are many tobacco-related health outcomes for which no comprehensive, geographic surveillance system exists, and a great limitation is that such surveillance systems are costly, especially for national ascertainment of tobacco and PREP-related illnesses. However, these are the most common and important preventable conditions and the investment seems justified. Decreasing the sample sizes in national population surveys or limiting population coverage may cause compromises in data quality or generalizability. A related issue is that it might take very large population surveys to adequately cover important demographic subgroups of interest, such as pregnant women or certain minority groups. Thus, it may be more efficient to have separate surveys or surveillance surveys of special populations than only one large population survey. A comprehensive surveillance system, as described in this chapter, could also be critical for other disease control activities that are not tobacco-related, and conceivably the cost of the system could be shared.

Another important limitation is that many aspects of population surveillance depend largely on self-report, which can be subject to error. In some instances, tobacco product usage can be validated by external means, but not in all circumstances. There are also limitations to predicting behaviors based on self-reported personal knowledge and attitudes, although both are important. Here, too, there are mechanisms to improve the validity of these reports.

There may not be suitable or logistically feasible biomarkers of exposures for the range of important tobacco products and toxicants to which users are exposed. Some of the biomarkers of exposure used in the past, such as cotinine, may still have utility for assessing conventional tobacco product exposure, but as new PREPs come to the marketplace, these markers may no longer be fully suitable because they won't necessarily serve as adequate surrogate markers for the range of major tobacco constituents.

Some elements of a comprehensive surveillance system, such as mandating tobacco manufacturers to report product characteristics, ingredients, additives, and brand-specific sales and distribution data might require a legislative or regulatory approach to enforce. Without this information, a comprehensive surveillance program would be much weaker.

Finally, it should be noted that it is not the burden of surveillance systems *per se* to relate PREPs or other tobacco product exposure to specific health outcomes or altered levels of those outcomes. That is usually the function of targeted epidemiological studies such as cohort studies of persons using PREPs to monitor for long-term health effects, with suitable contrast groups. Well-designed case-control studies may also be appropriate vehicles for exploring certain tobacco-disease associations, although the retrospective recall of the past product usage may not always be credible. As always, epidemiological studies should be accompanied by the best basic science and clinical research to guide the study design, apply the most modern markers of exposure and disease, and optimally interpret the findings.

SUMMARY AND RECOMMENDATIONS

The goal of the proposed surveillance system and accompanying epidemiologic studies is to provide much of the data need to determine the ongoing contribution of tobacco products, and

- Assessing various types of biological function can summarize the net biological and clinical impact of environmental exposures across several organ systems and anatomic sites. For example, common physical functions such as the ability to jog or carry groceries are dependent in part on cardiac, pulmonary, musculo-skeletal and neurological function.
- Various measures of mortality can be of use in addition to cause-specific death rates. The overall mortality rate is increased among cigarette smokers and effect of PREPs should be evaluated in this regard. A mortality assessment approach that combines age-specific mortality rates with general social functioning, such as in the "Years of Potential Life Lost," (Lai and Hardy, 1999) which has been used for several specific causes of death, might be considered. Mortality outcomes may also have an impact on other summary measures of health outcome and the quality-of-life (CDC, 2000A).
- Self-reported health status can be an important summary measure of both general physical health, as well as mental and social functional problems (Cott, 1999). A variation that has proven useful occurs when individuals are allowed to assess changes in their health status, such as might occur after a clinical intervention (Fischer et al., 1999).
- There are a number of multivariate approaches to determining general health status, going under the general term "health-related quality-of-life," reflecting symptoms, conditions, dysfunctions, behaviors, and biological markers. These measures have found application in both the clinical and public health settings (Hennessy et al., 1994; Tsevat et al, 1994). Some measures combine a large number of diverse health domains, such as the "SF-36" (Ware, 1992) and others combine measures of function with mortality (Tsuchiya, 2000).

Other measures exist that can't be summarized here. However, it seems important to define aggregate health measures that are sufficiently comprehensive and sensitive to the changing constituents of new tobacco products, in order to define health problems in global as well as specific terms.

Surveillance systems can also be used to assess the prevalence of non-tobacco risk factors that influence tobacco-induced illnesses (e.g., alcohol use in head and neck cancers). The committee also sees this system as an opportunity to monitor behavioral patterns such as diet and elicit drug use. Although the Committee recognizes that available data do not support the hypothesis that illicit drug use increases as tobacco use decreases (Chaloupka et al., 1999; Frosch et al., 2000; Lê et al., 2000; Taylor et al., 2000), the committee notes the ease with which such data could be obtained and recommends surveillance of this undesirable outcome.

ISSUES AND LIMITATIONS REGARDING SURVEILLANCE SYSTEMS FOR ASSESSING TOBACCO-RELATED HEALTH OUTCOMES

One important issue is who would conduct surveillance on conventional tobacco products and PREPs. The types of data recommended above would almost preclude all surveillance being conducted by one organization or agency. It is likely that the elements of surveillance will come from many sources, and a coordinated effort will be needed to plan, assimilate and interpret information for reasons of efficiency and standardization. As noted elsewhere in this volume, it will be important to include all conventional tobacco products, since they become one critical reference for health outcome studies, and to monitor changes in these products themselves. A part of the surveillance system would be to validate manufacturer claims of product distribution, content and biological and clinical effects.

Another issue is the collection of ancillary information necessary to conduct credible epidemiological studies with disease outcomes, as suggested above. For example, understanding lung

Disease Outcomes

As noted above, there is no systematic, ongoing, national morbidity surveillance system for the major illnesses and conditions related to tobacco products, although elements of this information are available from representative federal sample surveys of Americans, regional disease registries and vital records. National morbidity data could in itself provide important insights into tobacco product and PREP outcomes, but could also be used for other analytical studies. For example, ecological comparisons of lung cancer mortality rates (from the National Vital Statistics System) with historical patterns of cigarette smoking (from the National Health Interview Survey)(e.g., Shopland, 1995; Mannino et al., 2001) are consistent with the interpretation that historical smoking patterns strongly influence rates of lung cancer. Similar analyses to assess the influence of PREPs, would be more problematic and would thus require a variety of specific epidemiological studies that would not be part of routine surveillance, in part because of the duration between exposure and disease outcomes, and the complexity of multiple product exposure. For lung cancer and chronic obstructive lung disease, mortality data could serve as useful proxies of disease incidence.

As part of a comprehensive scientific program to determine the relation of PREPs to disease outcomes, analytical epidemiological studies would provide most robust and direct findings. As an example, cross-sectional surveys of tobacco product utilization could be turned into population-referent cohorts for determining health outcomes according to types of tobacco or PREP consumed, with over-sampling of persons who use new products. Surveys could also provide the data for case-control studies. A related case-control approach would be to append specific smoking histories to cancer and other disease surveillance systems, with suitable control populations.

For many policy and regulatory purposes, it may be sufficient to know whether PREPs have clinically and epidemiologically important and significant effects on occurrence and mortality for important individual chronic illnesses such as lung cancer, heart attack and chronic obstructive lung disease. However, there are several reasons why addressing these outcomes alone may be an insufficient approach to determining harm reduction potential: this approach does not document symptom patterns, various organ system dysfunctions and the quality-of-life prior to the occurrence of a major chronic illness. As noted elsewhere in this volume, current tobacco products cause many other important health conditions as well as dysfunction and disability; and the effects of new tobacco products may be in opposite directions, causing lesser incidence of some but greater incidence of other outcomes.

Thus, in addition to specific major disease outcomes, more summary and inclusive measures of health status and outcomes should be used in assessing PREP effects. Those selected should be based on conceptual models of health status (Steinwachs, 1989) as well as the questions to be addressed and methodological considerations and impediments (McHorney, 1999). Some general approaches to these outcomes are suggested:

- Determining the occurrence of other important smoking-related conditions, such as osteoporotic fracture, low birth weight and cataract can inform the general nature of PREP outcomes.
- Surveying for the occurrence of various symptoms and syndromes related to smoking. Such chronic or persistent conditions such as cough, sputum production, back pain due to osteoporosis, skin lesions or discoloration, and healing time for surgical wounds and peptic ulcers may be important to individuals and to optimal function. Some of these outcome measures (e.g. cough, sputum production) also have the advantage of requiring a relatively short amount of time to develop.

nicotine replacement therapy. Finally, exposure to environmental tobacco smoke should be also be monitored at a level that can estimate the magnitude of population exposure. Whether through basic surveillance or special, it will important to have estimates, for each product, not only of lifetime exposure, but age-at-initiation, quantitative "person-years" assessments of exposure, including the ages at which these exposures occurred, and age-at-permanent-quitting. Quantitative exposure determinations will be central to understanding whether disease outcomes may have been altered by PREP use.

Tobacco product use, and specifically PREP use, should also be measured in an ongoing and systematic manner. One central question about the net population impact of PREP introduction is whether these products influence patterns of quitting. A comprehensive surveillance system should be able to characterize factors that influence quitting. For example, measuring stages-of-change, motivation to quit, dependence, personal relevance of possible harm from tobacco use, favorable and unfavorable attitudes toward smoking, misperceptions of both tobacco use and PREPs, and reasons for relapse among those who do would be particularly important. Relevant populations of interest include tobacco users who adopt PREPs, tobacco users who don't adopt PREPs, and ex-users at risk for relapse (Shiffman, 1999).

Ancillary prospective studies of representative populations could further inform PREP impact. These studies would ideally be set up prior to the introduction of these products. Baseline data on a number of relevant variables would provide researchers with information that may explain, at least in part, why some tobacco users adopt PREPs, others do not, and others simply quit. This study would need to measure and statistically control for other environmental factors (e.g., prices of tobacco products, policy changes, treatment options, and emerging medical information), thus making it difficult to clearly detect an independent effect for a PREP or set of PREPs. An additional limitation is that these studies would provide information after an undesirable event (e.g., reduced quitting), requiring regulators to attempt to ameliorate the harm already done (Shiffman, 1999). Nevertheless, detection of change in behavioral studies is more rapid than in studies of some of the health outcomes (e.g., lung cancer or emphysema).

Another central question is whether the introduction of PREPs influences the attractiveness of tobacco use among those who have never regularly used PREPs or other tobacco products, particularly adolescents. Only population surveillance of tobacco-naïve populations could address this issue. Again, studies ancillary to the regular surveillance system can provide important and relevant information. For example, Pierce and colleagues (1996) have demonstrated among adolescents the predictive validity of a measure of susceptibility to smoke, which combines the domains of intention to smoke and perceived ability to resist the offer of a cigarette by a best friend. Susceptibility to smoke could be used as an early indicator of future changes in initiation. Another important part of behavioral surveillance is to determine misperceptions about risks from use of tobacco and PREPs as well as attitudes about their use and about persons who use them. Monitoring of these indicators and incorporation of new measures as they develop will optimally assess changes in this construct.

The population-based surveys currently providing data to the public health community are generally released from seven to 24 months after data collection. In addition, questionnaire content is often inflexible. Prevention programming would be better served if smaller, but more frequent (e.g., monthly) tracking surveys were conducted to assess reactions to new products and campaigns (Giovino, 2000).

tices would assist in identifying new and existing potentially undesirable constituents (e.g., tobacco-specific nitrosamines), as well as new breeds or hybrids (including those genetically altered) of tobacco that may have implications for human health. There should be similar information on imported tobacco products. Additionally, surveillance of manufacturing practices, especially those involving ingredients, should be instituted.

Tobacco Product Marketing

The monitoring of tobacco product marketing and public relations strategies will provide policy makers with data upon which to base decisions about the accuracy of information presented to the public and health professionals. The FTC (or another agency) could release brand-specific marketing data, if permitted to do so by legislation. Systematic media and other marketing practice monitoring would allow the assessment of messages conveyed on television, the Internet and in movies, newspapers, magazines, and mass mailings. Some monitoring of the industrially produced technical information may be of value. Another important question is whether industry marketing and public relations strategies undermine explicit public policies, laws and regulations relevant to tobacco control.

While a research topic for further evaluation, routine message evaluation before release could provide early warnings of future problems. For example, Shiffman (1999) described two methods of testing messages. In the first, people from groups of concern (e.g., adolescents) are exposed to test stimuli and assessed for changes in attitudes, beliefs, and intentions. This system is generally conservative, as laboratory testing situations do not replicate the real world in terms of the number of repetitions of the test message or the number of different messages an individual receives on the same topic from numerous channels. Thus, any indications of future problems should be seriously considered, while false negatives may be common. In the second, expert qualitative analysis is employed to assess likely message impact.

Biomarkers of Exposure to Tobacco Products

Studies of biological fluids should be continued within the context of NHANES, which serves as a robust national sample survey that acquires serum and urine specimens. The specific biomarkers to be determined would evolve over time with scientific advancements, and would be aimed at biomarker-based determination of exposure to tobacco products in general, including environmental tobacco smoke, and to specific constituents that might allow determination of specific tobacco product usage or that have predictive value for tobacco-related diseases and conditions. Additional relevant biomarkers are suggested in Section II of this volume. In addition, special studies should be conducted to assess relevant biomarkers in special groups who may not be well-represented in representative national surveys, such as living in a test market area or pregnant women.

Personal Tobacco Product Use and Related Behavioral Patterns

Key predictors of tobacco product usage that are relevant to important changes in population morbidity and mortality, such as changes in prevalence of use, initiation occurrence rates, product quitting behavior rates and patterns of relapse, should be carefully monitored. Detailed measures of lifetime product use patterns are also needed. Studies of product usage in special populations, such as pregnant women, should be considered as a matter of routine, as well the use of

sessed. Further, tobacco usage histories on vital record documents has not been fully validated, and linking mortality to tobacco product use generally requires special studies.

Other Surveillance Activities: The Social and Legislative Environment

Current systems monitor state and local legislation and programmatic activities (CDC, 2001; Robert Wood Johnson Foundation, 2001; Stillman et al. 1999); exposure to pro-health messages (Robert Wood Johnson Foundation, 2001); and tobacco placement in stores, promotions, and prices (Robert Wood Johnson Foundation, 2001). NCI's ASSIST project monitors newspaper stories and editorials, permitting assessment of the print media's coverage of and policy on tobacco control activities (Stillman et al., 1999).

PROPOSED SURVEILLANCE SYSTEM ENHANCEMENTS

The overriding goal of a surveillance system on PREPs should be to maximize the ability to assess the public health impact of the introduction of these products, with the explicit goal of maximizing the health of the public. As derived from the elements of an ideal surveillance system noted in the introduction to this chapter, and existing surveillance activities noted above, the following are suggestions for new or enhanced components to these existing activities.

Consumption of tobacco products and PREPs

State and regional information on the consumption of various products would provide useful information, especially if reported on a monthly or quarterly basis. In addition, future reporting systems that include PREPs may also need to be based on milligrams of nicotine consumed per product, as pounds of tobacco may become a less complete marker of consumption.

Specific Tobacco Constituents of Both the Products and the Smoke They Generate

At the time of PREP and other new product release, there should be detailed, manufacturer-derived information on important and major physical and chemical constituents of all tobacco products, including additives and the structural components of the products, such as filters, fibers and fragments of fibers. Some independent post-marketing monitoring of product constituents may be necessary to ensure that changes are known to the public and the scientific community. For example, a recent letter from the Commissioner of the Massachusetts Department of Public Health to the Chairman of the Federal Trade Commission (Koh, 2000) highlighted the need for such monitoring. Koh points out that R.J. Reynolds' Eclipse™ product produced higher concentrations of toxic chemicals in 2000 than in 1996, suggesting that consumers would need to be informed of the added dangers from the 2000 version of the product. More details and specific recommendations can be found in Chapter 7, Implementation of a Science-Based Policy of Harm Reduction.

Product constituents can be influenced by agricultural and manufacturing practices. There is currently no systematic surveillance of agricultural practices or curing processes that can influence levels of undesirable constituents (e.g., tobacco-specific nitrosamines), as well as new breeds or hybrids (including genetically-altered) of tobacco that may have implications for human health. Hence, there should be enhanced monitoring of tobacco agricultural practices. General data on the types and amounts of tobacco harvested, as well as curing and processing prac-

Monitoring the Future (MTF) surveys of 8th, 10th, and 12th grade students (Monitoring the Future, 2001), and the National Household Survey on Drug Abuse (NHSDA) (SAMHSA, 2000). The NYTS is a categorical survey, dedicated to measuring tobacco-related knowledge, attitudes, and behaviors in middle and high school students. The MTF and the NHSDA are primarily designed to measure illicit drug use, with more limited coverage of tobacco. NHSDA surveys persons aged 12 years old and older. The Youth Risk Behavior Survey (YRBS) (NCCDPHP, 2001b) measures health risk behaviors in high school students. Several states conduct their own versions of the YRBS (Kahn, 1998) and the Youth Tobacco Survey (U.S. DHHS, 2000). MTF includes a longitudinal component, but only for 12th grade students (Johnston et al 2000).

Three major national surveys of adults (persons aged 18 years and older) ascertain tobacco-related knowledge, attitudes, and behaviors (Table 6-1). The National Health Interview Survey (NHIS) measures several tobacco use indicators on the core instrument every year, and assesses knowledge, attitudes, and additional behavioral measures on periodic supplements (NCHS, 2001). The NHSDA questions for adults are similar to those for adolescents. The National Cancer Institute Tobacco Use Supplement of the Current Population Survey (CPS) provides measures of tobacco-related knowledge and behaviors, as well as opinions about various tobacco control policies for all states and the District of Columbia (Gerlach et al., 1997). In addition, the Behavioral Risk Factor Surveillance System (BRFSS), a set of coordinated statewide health behavior surveys, queries self-reported tobacco use in all states and the District of Columbia (NCCDPHS, 2001a). BRFSS is developing the capacity to provide small area estimates. As noted above, the NHANES assesses adult use and serum cotinine values to biochemically validate active use and assess exposure to environmental tobacco smoke.

Two ongoing surveys provide information on tobacco and reproductive health issues. The National Survey of Family Growth surveys women 15- 44 years of age to assess factors affecting pregnancy and women's health (National Vital Statistics System, 2001). The Pregnancy Risk Assessment Monitoring System (PRAMS) provides representative data from 23 states on maternal attitudes, behaviors, and experiences in order to reduce adverse outcomes of pregnancy (NCCDPHP, 1999).

Disease Outcomes

Since tobacco product use has been linked to so many different diseases and conditions, reviewed elsewhere in this report, national determination of tobacco-related morbidity assessment would be a daunting task. For example, not all states have comprehensive cancer surveillance, the most complete of which is sponsored by the registries of the US National Cancer Institute (NCI, 2001) and the CDC cancer surveillance program (CDC, 1999). In addition, birth certificates for such issues as low birth weight (NVSS, 2000), and data from surveys of hospital discharges (Agency for Healthcare Research and Quality, 2000) and medical expenditures (MEPS, 2001) could be used. There is no ongoing national surveillance of incident heart disease and stroke, chronic lung disease, osteoporotic fractures or most other tobacco-related health outcomes. However, the NHIS and the NHANES do assess self-reported conditions on a regular basis, sometimes supplemented with physiological measurements.

The National Vital Statistics System coordinates data from state operated registration systems (NVSS, 2000). Many states assess tobacco use on the death certificate and other vital records. The universal vital record system in the United States can be extremely useful for tobacco-related outcomes that often lead to death, but leaves the remaining important outcomes unas-

Specific Tobacco Constituents of Both the Products and the Smoke They Generate

Currently, there is no US nation-wide reporting by tobacco manufacturers of the physico-chemical content of tobacco products, nor of additives or structural components. The Federal Trade Commission (FTC) reports on the results of testing of cigarette brands for tar, nicotine, and carbon monoxide (e.g., FTC, 2000a). However, as described elsewhere (Chapter 11), the usefulness of this system has been challenged (NCI, 1996).

The National Center for Environmental Health at CDC is building capacity for monitoring and research on various aspects of product design, including studies of tobacco, tobacco smoke, and biomarkers in human body fluids. Other laboratories (e.g., the American Health Foundation) have the capacity to perform tests of tobacco constituents and combustion product exposure, but they also do not conduct population surveillance.

In the Commonwealth of Massachusetts, cigarette companies (Brown and Williamson Tobacco Company, Lorillard Tobacco Company, Philip Morris USA, and R.J. Reynolds Tobacco Company) provide benchmark indicators on a sample of cigarette brands deemed representative of the U.S. market (Borgerding, 2000). The 1999 Massachusetts Benchmark Study investigated the functional relationships between standard smoke-yield parameters (e.g., "tar," nicotine, and carbon monoxide) and selected smoke constituent (e.g., acetaldehyde, 4-Aminobiphenyl, arsenic, and benzene) yields. Measures were taken on both mainstream and sidestream smoke. However, there are regional variations in tobacco product use and no national system of tobacco product distribution and consumption is in place.

Tobacco Product Marketing

No comprehensive surveillance system exists for monitoring industrial activities. The Federal Trade Commission annually collects brand-specific data but reports only aggregated national data on industry marketing expenditures (FTC, 2000b), in part obtained by subpoena. Several researchers analyze and report industry lobbying, sponsorship, and public relations activities (Glantz and Begay, 1994; Glantz et al., 1996; Siegel, 2000).

Biomarkers of Exposure to Tobacco Products

The National Health and Nutrition Examination Survey (NHANES) assesses self-reported tobacco use and serum cotinine levels annually on nationally representative samples of children, adolescents, and adults (NCHS, 2000). Determination of serum cotinine levels, a nicotine metabolite, permits biochemical validation of active use and assessment of environmental tobacco smoke exposure in persons who don't use tobacco products. However, there is insufficient but growing ascertainment of specific tobacco product brands or detailed smoking behaviors. The National Center for Environmental Health at CDC is building capacity for monitoring and research on tobacco products, including studies of biomarkers in human body fluids.

Personal Tobacco Product Use and Related Behavioral Patterns

Since most tobacco use initiation occurs among adolescents, their knowledge, attitudes and usage patterns become an important part of tobacco and PREP assessment. Three major national surveys of adolescents exist that measure at least some tobacco-related knowledge, attitudes, and behaviors (Table 6-1). These are the National Youth Tobacco Survey (NYTS) (TIPS, 2000), the

posure to tobacco constituents may not be fully ascertained from self-report due to variation in smoking behavior and use patterns (i.e., smoking topography). Biomarkers can also provide indication of the degree of exposure to environmental tobacco smoke among non-tobacco users. For these and other reasons, population levels of biomarkers of exposure become extremely important.

5 *Personal tobacco product use and related behavioral patterns.* Critical to assessing the health impact of conventional tobacco products and PREPs is the determination of actual products used, including product types and brands. It is also important to understand the impact of PREPs in terms of smoking initiation, quit attempts, maintained abstinence, and personal consumption patterns (Shiffman, 1999). In general, this can only be determined from sample surveys of relevant populations. Attitudes toward tobacco usage and knowledge of actual threats to health would also be important components of such a system.

6 *Disease outcomes.* Current surveillance of tobacco-related illnesses through mechanisms such as vital records and disease registries provide important information. The development of additional types of registries, clinical record monitoring systems, and systems measuring aggregate health outcomes would add further useful information. Supplementary epidemiological studies of PREPs would enhance the ability to determine specific health outcomes. These studies would deal with use of various product lines and with potential confounders and effect modifiers of the associations. Surveillance and other long-term studies are necessary because of the duration of exposure before many chronic diseases appear. These adverse outcomes would include the health consequences that are expected based on the toxicological profile of the PREP, as well as those that are unexpected.

EXISTING TOBACCO SURVEILLANCE SYSTEMS

This section highlights existing systems of surveillance that monitor tobacco product consumption patterns, knowledge, attitudes, behaviors, and health consequences--elements that would inform the evaluation of PREP usage and impact (Giovino, 2000). The section emphasizes national and state level systems. It is possible that local or regional systems may add considerable useful information. Citations or web sites are provided for the reader who desires more detailed information.

Consumption of tobacco products and PREPS

The U.S. Department of Agriculture reports consumption data for the various types of tobacco products (USDA 2000; ERS, 2001). FTC also reports on the characteristics of cigarettes (e.g., length, filtered/non-filtered, mentholated/nonmentholated) sold in the United States (FTC, 2000a). At least one research unit (the Roswell Park Cancer Institute's Department of Cancer Prevention, Epidemiology and Biostatistics) has begun to monitor the introduction of new products.

Surveillance for the Health and Behavioral Consequences of Exposure Reduction

The goal of surveillance systems in epidemiology and public health is to provide timely information from populations on the occurrence of diseases and conditions of interest, the presence of risk factors for those conditions and the impact of disease control programs. Public health surveillance systems are not the only sources of information on the frequency or causes of various disease nor are they the only indicators of disease control program success or failure, but the population perspective brings focus to the entire community and the totality of the burden of suffering from various conditions.

The Centers for Disease Control and Prevention (CDC) offers the following definition of surveillance (Thacker and Berkelman, 1988):

> "Public health surveillance is the ongoing, systematic collection, analysis, and interpretation of health data essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those who need to know. The final link in the surveillance chain is the application of these data to prevention and control. A surveillance system includes a capacity for data collection, analysis, and dissemination linked to public health programs."

The extent and sophistication of surveillance systems have evolved over the years (Remington and Goodman, 1998). At the turn of the 20th Century, they largely involved monitoring of persons with particular infectious diseases and their personal contacts, such as surveillance of persons who came in contact with smallpox or typhus cases. By mid-century, they evolved into monitoring a wide variety of communicable diseases for detection and control purposes. Selected chronic illnesses became the target of surveillance programs beginning in the 1970s. Later, a host of surveillance techniques were used to monitor environmental exposures such as hazardous occupations, personal injuries and health-related individual behaviors. Tobacco use was first studied in a federal survey in 1955 (Haenszel et al, 1956). In 1996, the Council of State and Territorial Epidemiologists added the state-specific prevalence of cigarette smoking to the list of conditions designated as notifiable by states to the CDC (CDC, 1996).

Among the attributes that are used to evaluate surveillance systems are simplicity, flexibility, acceptability, sensitivity, representativeness, and timeliness (Klaucke et al., 1988). The *simplicity* of a given surveillance system is influenced both by its structure and ease of operation. A given surveillance system will ideally be as simple as possible and still meet all of its objectives. A *flexible* system can economically adapt to changing information needs or operating conditions. *Acceptability* refers to the willingness of organizations and individuals to adopt and/or participate in the surveillance system. In this instance, acceptability will be influenced by whether the sys-

tem is mandated. *Sensitivity* refers to the ability of a system to detect diseases and conditions, health states or various health behaviors or attitudes of interest. A *representative* surveillance system will accurately describe the distribution of a health event by person, place, and time. A *timely* system minimizes the delay between occurrence of an event and the initiation and completion of the process of monitoring and reporting of findings.

Another important attribute of surveillance systems is whether the detection targets are collected *actively* or *passively*. Passive surveillance generally involved the collection of spontaneously reported health events from interested health professionals or others. The current system of reporting adverse drug events to the Food and Drug Administration generally falls into this category. On the other hand, active surveillance involves expending the resources to marshal all available data collection modes to assure as complete an ascertainment as possible of the health and behavioral events of interest. Active surveillance would seem to be essential for helping to assess the impact of PREPs in population context.

This chapter reviews existing surveillance systems and activities for monitoring tobacco product exposure and their health consequences, with emphasis on the introduction and use of PREPs and the issue of harm reduction in the United States. Then proposals to enhance existing surveillance programs are offered. While surveillance data provide only one part of the information needed for scientific and regulatory judgments, it is a critical component that complements clinical, basic and other data collection. In general, a successful surveillance activity would determine amounts and types of tobacco products distributed in the community, population patterns of product use and rates of smoking-related conditions. Specifically, an ideal surveillance system for evaluation of PREPs and other tobacco products would contain the following elements:

1 *Consumption of tobacco products and PREPs.* A first step to understanding changes in tobacco-attributable diseases and the impact of control programs is to monitor consumption rates for conventional tobacco products and PREPs. The federal government has monitored per capita consumption (in pounds) of tobacco products for over a century (Milmore and Conover, 1956; USDA, 2000). National estimates of consumption use overall include sales data and are adjusted to incorporate estimates of smuggling. Information on the use of pharmaceutical aids for smoking cessation has been published recently (CDC, 2000).

2 *Specific tobacco constituents of both the products and the smoke they generate.* Central to any surveillance system is accurate characterization of environmental exposures of interest. With respect to conventional tobacco products and PREPs, documenting the physical and chemical content of these products, including additives and structural components, is critical. It is equally important to determine the constituents of the products of tobacco product combustion and other elements otherwise delivered during human consumption.

3 *Tobacco product marketing, including PREPs.* This is similarly extremely important to understand the distribution and availability of PREPs in the community. For example, monitoring of general media advertising, free-sample distribution and other marketing practices including mass mailings and public relations activities would seem essential to monitor any health claims, implicit or explicit, related to PREPs as well as conventional tobacco products.

4 *Biomarkers of exposure to tobacco products.* Depending fully on personal self-report of tobacco product use is important but not always sufficient. On occasion, individuals may mis-represent their tobacco exposure or may not be fully aware of it. Further, bodily ex-